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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,315	HORAN ET AL.	
	Examiner	Art Unit	
	Thomas Mcevoy	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) *69-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/17/2004 and 10/14/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/01/04, 08/18/04, 11/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is the initial Office Action on the Merits based on the 10/779,315 application filed on February 17th, 2004. Claims 1-39 and 41-68, elected for examination, are currently pending and have been considered below.

Election/Restrictions

2. Applicant's election without traverse of the invention of group I (claims 1-68) and Species 1, claims 1-39 and 41-68, in the reply filed on November 21, 2007 is acknowledged.

Claim Objections

3. Claims 14, 21-25, 50 and 61 are objected to because of the informalities listed below. There is insufficient antecedent basis for these limitations in the claims. Appropriate correction is required.

Claim 14 recites the limitation "delivery sheath". Examiner has determined this limitation to mean "distal sheath" for the purpose of this examination.

Claims 21-22 recite the limitation "exit port". Examiner has determined this limitation to mean "guidewire exit port" for the purpose of this examination. Claim 21 also recites the limitation "abutment region".

Claims 23-25 recite the limitation "distal sheath".

Claim 50 recites the limitation "distal outer sheath". Examiner has determined this limitation to mean "distal sheath" for the purpose of this examination.

Claim 61 recites the limitation "operator handle".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "high compressive stiffness" renders the claim indefinite in that it is not clear what constitutes being "high compressive stiffness". It is unclear whether this is a compression feature or a bendability feature.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6-8, 23-28, 30, 32, 39, 41, 43-47, 50-53 and 57-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al. (US 6,126,685).

Regarding claim 1: a delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising; a catheter shaft (Figure 7 #72) having a proximal end and a distal end, the distal end of the shaft defining a reception space (Figure 7, stent "P" is held within the lumen of #72) for receiving a self expanding stent, the stent having a reduced diameter delivery configuration [the stent (Figure 7, "P") fits into the distal end of a sheath (Figure 7, #78)

in a reduced diameter (column 7, lines 44-45)**]**; an inner core engagable with the proximal end of the stent **[**As can be seen in Figure 2, the stent is disposed about, and therefore completely engaged by, the inner core (#34), which further engages the stent at the proximal end with stay members (#50)(column 7 - lines 39 to 65)**]**; an operator handle for movement of the catheter shaft relative to the inner core to deploy the self expanding stent (Figure 6 #40); a stabiliser component (Figure 6 #60); the inner core being fixed to the stabiliser component, at least during deployment of the self expanding stent (Figure 6, column 7 – line 66 to column 8 – line 13).

Regarding claim 2: a delivery system as claimed in claim 1 wherein the inner core has an abutment which is engagable with the proximal end of the stent to deploy the stent **[**as described in regard to claim 1 (Figure 2 #50)(column 7 - lines 39 to 65)**]**.

Regarding claim 3: a delivery system as claimed in claim 2 wherein the inner core has a reduced diameter distal portion extending distally of the abutment at least partially through the stent in the reduced diameter delivery configuration of the stent **[**the inner core can have an enlarged tip for anchoring the stent (column 7 – lines 31-35, Figure 19 #256) thus creating a reduced diameter distal portion extending through the stent and abutment region**]**.

Regarding claim 4: A delivery system as claimed in claim 3 (addressed above) wherein the inner core forms a tubular member in the region of the abutment **[**the inner core is clearly a tubular member at its distal end (Lenker, Figure 2 #42) where the abutment (#50) is positioned**]**.

Regarding claim 6: a delivery system as claimed in claim 5 (addressed above) wherein the inner core is of a composite, or a metallic construction **[**although it is not clear what defines "high compressive stiffness", the catheter may be made of polymer (Lenker, column 8 – lines 29-44)**]**.

Regarding claim 7: a delivery system as claimed in claim 1 wherein the catheter shaft comprises a distal sheath and a stent is frictionally coupled to the distal sheath in the delivery configuration **[**the stent ("prosthesis") is radially compressed by the sheath (Abstract)**]**.

Regarding claim 8: a delivery system as claimed in claim 7 wherein the inner core has an abutment which is engagable with the proximal end of the stent to decouple the stent and distal sheath to deploy the stent **[**as described in regard to claim 1 (Figure 2 #50)(column 7 - lines 39 to 65)**]**.

Regarding claim 23: a delivery system as claimed in claim 1 wherein the stent directly engages the distal sheath and is slidable relative to the sheath **[**the sheath radially compresses the stent (column 7 – lines 29 to 31); the stent is prevented from sliding out of the deployment area by anchors or stay members, therefore it is slidable (column 7 – lines 39 to 41)**]**.

Regarding claim 24: a delivery system as claimed in claim 23 wherein the distal sheath is a composite with a low friction inner surface **[**the term "low friction is not clearly defined and therefore, the frictional engagement of the distal sheath with the stent in order to release the stent (as discussed for Lenker et al. in regard to claim 7) shows that the inner surface has low friction under the broadest reasonable

interpretation of the term; furthermore, the catheter may be a composite (column 8 - lines 29 to 38)**]**.

Regarding claim 25: a delivery system as claimed in claim 24 wherein the distal sheath is reinforced to withstand the radial stresses of the stent in its constrained reduced diameter configuration (column 8 - lines 29 to 38).

Regarding claim 26: a system as claimed in claim 1 wherein the inner core is fixed to a component of the delivery system **[**the inner core can be fixed to the stabilizer (journal sleeve)(columns 7 to 8 – lines 66 to 3)**]**.

Regarding claim 27: a system as claimed in claim 1 wherein the component of the system to which the inner core is fixed comprises the handle**[**the inner core can be fixed to the stabiliser (journal sleeve)(columns 7 to 8 – lines 66 to 3) which surrounds the proximal end of the catheter and therefore can be grasped, where the catheter of the reference does not require another sheath for insertion and operation, where movement of the stabiliser can move the inner core relative to the catheter shaft**]**.

Regarding claim 28: A system as claimed in claim 1 wherein the stabiliser component is fixed to a procedural catheter **[**the stabiliser (journal sleeve) may be fixed to an introducer sheath (columns 7 to 8 – lines 66 to 6)**]**.

Regarding claim 30: a system as claimed in claim 28 wherein the catheter is an introducer sheath **[**the stabiliser (journal sleeve) may be fixed to an introducer sheath (columns 7 to 8 – lines 66 to 6)**]**.

Regarding claim 32: a system as claimed in claim 28 wherein the procedural catheter is a guide catheter **[**the stabiliser (journal sleeve) may be fixed to an introducer

sheath (columns 7 to 8 – lines 66 to 6) where an introducer sheath serves to provide a passage, or guide the catheter, percutaneously; further noting that no definitive example has been given to differentiate the terms**]**.

Regarding claim 39: a system as claimed in claim 1 wherein the stabiliser component position is adjustable **[**the catheter extends outside of the patient and therefore can be position adjusted when in use (columns 7 to 8 – lines 66 to 9)**]**.

Regarding claims 41, 43-47: a system as claimed in claim 1 wherein an intermediate component is provided between the stabiliser component and the inner core; a system as claimed in claim 41 wherein the intermediate component comprises at least one bridging piece; a system as claimed in claim 43 wherein the bridging piece extends through the wall of the proximal shaft; a system as claimed in claim 44 wherein the bridging piece projects laterally of the inner core and/or the stabiliser component; a system as claimed in claim 45 wherein the bridging piece projects radially between the inner core and the stabiliser component; a system as claimed in claim 1 wherein the stabiliser component and the inner core are directly mounted to one another; **[**a pin projects radially/laterally between and connects the stabiliser (journey sleeve) to the inner core (Figure 6 #34)(column 7 – line 66 to column 8 – line 13)**]**.

Regarding claims 50-51: a system as claimed in claim 47 wherein the stabiliser component and the inner core are directly mounted to one another proximal of the distal outer sheath; a system as claimed in claim 50 wherein the stabiliser component and the inner core are directly mounted to one another proximal of the outer shaft**[**as can be seen in Figure 6, the inner core (#34) and stabiliser (#60) can be mounted to one

another proximally of the distal end of the catheter where the catheter shaft can comprise a short section of tubing at the distal end of the catheter connected by a pull-wire (Figure 22B)**]**.

Regarding claims 52-53 and 57-59: a system as claimed in claim 1 wherein the system includes a guidewire and the guidewire extends at least the length of the catheter shaft; a system as claimed in claim 52 wherein the inner core defines a guidewire lumen along the length thereof; a system as claimed in claim 1 wherein the system includes a guidewire and the guidewire is located within the profile of the stabiliser component; a system as claimed in claim 1 wherein the stabiliser component has a proximal opening to allow backflow of blood; a system as claimed in claim 1 wherein the stabiliser component extends substantially the length of the catheter shaft. **[**as can be seen in Figure 19, the catheter can contain a guidewire which extend within and through the inner core (#252 or #35) and past the catheter shaft (or sheath); the sheath can be contained within the stabilizer which can extend a significant length thereof (Figure 7 #76)**]**.

Regarding claims 60-63 and 67: A delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising: a catheter shaft having a proximal end and a distal end, the distal end of the shaft defining a reception space for receiving a self expanding stent, the stent having a reduced diameter delivery configuration; an inner core engagable with the proximal end of the stent; an external mounting for the inner core; and an operator actuating element for the catheter shaft; the operator actuating element being movable proximally of the

external mounting for movement of the catheter shaft relative to the inner core to deploy the self expanding stent; a delivery system as claimed in claim 60 wherein the operator handle is a pull handle for pulling the catheter shaft proximally relative to the inner core to deploy the self expanding stent; a delivery system as claimed in claim 60 wherein the catheter shaft and the operating handle or interconnected by a connector; a delivery system as claimed in claim 62 wherein the connector extends proximally of the external mounting; a delivery system as claimed in claim 60 wherein the inner core is fixed internal of the external mounting **[**(all limitations not addressed here have been addressed in regard to claim 1) as can be seen in Figure 6, the journal sleeve #60 is the external sheath and connected (mounted to) the inner core (#34) through an internal connection; the catheter shaft (#32, mislabeled #34, see column 8 – lines 2 to 3) has a handle #40 (which is inherently connected to the shaft by a connector) which can be used to slide (or pull) the catheter shaft proximally of the journal sleeve (or stabiliser, or external mounting) and inner core to deploy the stent (Figures 3-5, column 7 – lines 49 to 52)**]**.

Regarding claims 64-66: a delivery system as claimed in claim 63 wherein the connector extends through the external mounting; a delivery system as claimed in claim 62 wherein the connector comprises an elongate member; a delivery system as claimed in claim 65 wherein the elongate member comprises a pull wire**[**the catheter shaft can comprise a short section of tubing at the distal end of the catheter connected by a pull-wire (Figure 22B, column 12 – lines 6 to 17), the pull wire is shown to extend parallel to

the inner shaft and inherently would be drawn through the journal sleeve (or external mounting)**]**

Regarding claim 68: a delivery system as claimed in claim 60 wherein a guidewire exit port is provided at the proximal end of the external mounting **[**Figure 19 shows that the inner core (#256) can contain a guidewire and since the inner core exits through the stabiliser (Figure 6 #60) so must the guidewire**]**.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 9-11 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Leschinsky (US 6,306,145).

Regarding claim 9-11 and 18-19 Lenker et al. teach: A delivery system as claimed in claim 1 (as described above); wherein the stabiliser component is disposed over the smaller diameter proximal shaft **[**it can be clearly seen that the stabilizer (Lenker, Figure 6 #60) is disposed over the catheter shaft (#32)**]**.

Lenker et al. do not teach: wherein the catheter shaft comprises a distal sheath portion and a proximal shaft portion, the diameter of the proximal shaft portion being smaller than the diameter of the distal sheath portion; wherein the stabiliser comprises a tube and the diameter of the stabiliser tube is not greater than the diameter of the distal sheath of the catheter shaft; wherein the system comprises a guidewire and the sum of the diameter of the guidewire and the diameter of the proximal shaft is less than the diameter of the distal sheath; wherein the sum of the diameter of the guidewire and the diameter of the stabiliser component is less than the diameter of the distal sheath.

Attention is drawn to Leschinsky who teaches that it is advantageous to construct a catheter with a distal sheath portion which is of greater diameter than the proximal shaft portion and of equal or greater diameter to the introducer sheath (or stabiliser) so that the introducer sheath can be inserted without increasing diameter of the skin puncture, which would minimize trauma to the patient, and so that smaller sized catheters can be used in order to minimize blood flow restriction (Abstract, column 2 - lines 21 to 34, column 5 – lines 65 to 67).

It would therefore be obvious to one of ordinary skill in the art, having the teachings of Lenker et al. and Leschinsky before him or her, to combine the invention of Lenker with the reduced diameter proximal shaft and stabliliser of Leschinsky, in order

to minimize trauma to the patient and minimize blood flow restriction, where the stabilizer is of less diameter than the distal sheath in order to easily fit through the puncture site used by the distal sheath. To further teach the limitations of the claims (which are already met by the above description), the invention of Lenker could be used in a rapid exchange configuration, which would be an obvious design choice to one of ordinary skill in the art, where the guidewire is external to the catheter shaft except at the distal end. In this arrangement, the sum of the guide wire diameter and stabilizer diameter would have to be less than the diameter of the distal sheath.

11. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Leschinsky (US 6,306,145) and in further view of Healy et al. (EP 1095634).

Regarding claims 12 -17, Lenker et al. in view of Leschinsky teach: A delivery system as claimed in claim 9 (as discussed above).

Lenker et al. do not teach: wherein the catheter shaft has a guidewire exit port which is located proximally of the distal end of the catheter shaft; a delivery system as claimed in claim 12 wherein the guidewire exit port is located proximally of the stent; a delivery system as claimed in claim 12 wherein the guidewire exit port is located proximally of the delivery sheath; a delivery system as claimed in claim 12 wherein he guidewire exit port is located at a transition between the distal sheath and the reduced diameter proximal shaft portion; a delivery system as claimed in claim 12 wherein the guidewire exit port is located distally of the stabiliser component; a delivery system as

claimed in claim 12 wherein the guidewire exit port is configured to exit along an axis that is substantially parallel to a longitudinal axis of the distal sheath.

Attention is drawn to Healy et al. who teach a rapid exchange catheter configuration where the guidewire exit port is at an intermediate, transition section (Figure 2 #46) of the catheter shaft, just prior to the delivery sheath (Figure 2 #30 and #28) and distally of the stabilizer (column 10 – lines 52-55) where it exits in a line that is substantially parallel to a longitudinal axis of the distal sheath (Figure 1 #44). This design addresses the challenge of maintaining alignment of the inner and outer guidewire ports (column 5 – lines 10-11).

It would be obvious to one of ordinary skill in the art, having the teachings of Lenker et al., Leschinsky, and Healy et al. before him or her, to combine the invention of Lenker et al. with the guidewire port configuration of Healy et al. in order to have the operational advantages of a rapid exchange catheter and minimize misalignment of the guidewire exit port during sheath retraction.

12. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Blaeser et al. (US 6,168,617).

Regarding claims 20-22 Lenker et al. teach: a delivery system as claimed in claim 1 wherein the inner core comprises a large diameter distal segment and a reduced diameter proximal segment (as described above for claim 3).

Lenker et al. do not teach: a transition segment between the distal and proximal segments; a delivery system as claimed in claim 20 wherein the transition segment is

proximal of the abutment region; a delivery system as claimed in claim 20 wherein the transition segment is distal of the exit port.

Attention is drawn to Blaeser et al. who teach a catheter with an inner core (Figure 2 #18) having a reduced diameter transition portion extending through the stent (Figure 2 #40) in order to reduce the overall diameter of the catheter at the distal end to facilitate ease of movement through arteries and lesion sites (column 2 – lines 46 to 59).

It would therefore be obvious to one of ordinary skill in the art, having the teachings of Lenker et al. and Blaeser et al. before him or her, to have reduced the diameter of the inner core further, at least through the stent engaging section which includes abutments (as described for claim 2), in order to reduce the diameter of the distal end of the catheter which would facilitate its movement through arteries and lesion sites.

13. Claims 29, 31, 33-36 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view Lenker et al. (same reference) and in further view of Burns (US 5,032,113).

Regarding claims 29, 31, 33-36, and 54-55 Lenker et al. teach: a system as claimed in claim 1, 28 or 52 (as described above).

Lenker et al. do not teach: wherein a haemostasis gasket is provided between the stabiliser component and the procedural catheter; a system as claimed in claim 30 wherein the introducer sheath has an integral haemostasis gasket; a system as claimed in claim 32 wherein the guide catheter has a haemostasis gasket attachment; a system as claimed in claim 33 wherein the gasket is adjustable by the operator; a system as

claimed in claim 34 wherein the gasket attachment is a Touhy Borst; wherein the system comprises a procedural guidewire and the guidewire is fixed or fixable to the stabiliser component; wherein the system includes a lock for the guidewire; a system as claimed in claim 54 wherein the lock is located proximal of the handle.

Burns teaches that a manifold would contain Touhy Borst fittings to provide a hermetic seal for the guidewire and to lock the relative position of the guidewire and catheter tube (Figure 1A #21, column 4, lines 37-40).

The examiner further notes that Touhy Borst fittings in combination with a manifold can be used to fix the relative position of a catheter tube and guidewire or other catheter tube, whether the catheter tube is a stabiliser, introducer sheath or guide catheter makes no difference. Touhy Borst fittings contain gaskets and form a unitary, or integral, connection with tubes and guidewires.

It would be obvious to one or ordinary skill in the art and having the teachings of Lenker et al. and Burns before him or her to use a Touhy Borst fitting in combination with a manifold to hermetically seal a guidewire to the catheter thereby fixing it, indirectly, to the stabiliser. It would also be an obvious design choice to one of ordinary skill in the art to have connected the stabiliser of Lenker to an introducer sheath or guide catheter via a Touhy Borst fitting, in order to anchor the stabiliser to the introducer sheath or guide catheter as intended by Lenker et al. (columns 7 to 8 – lines 66 to 6).

14. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view Lenker (US 5,683,451).

Regarding claims 37-38: Lenker et al. teach a system as claimed in claim 1 (as described above).

Lenker et al. do not teach: wherein the stabiliser component is length adjustable; wherein the stabiliser component comprises at least two parts which are movable relative to one another.

Attention is drawn to Lenker et al. (US 5, 683, 451) who teach a catheter of very similar design to Lenker et al. (primary reference) where the stabiliser (Figure 2 #38) contains a slidable piece or slider (Figure 2 #50) which allows for length adjustment of the stabiliser so that it can be fit into an external control device (evident from Figure 33).

It would therefore be obvious to one of ordinary skill in the art and having the teachings of Lenker et al. and Lenker et al. before him or her to have combined the invention of Lenker et al. (primary reference) with the slider of Lenker et al. (secondary reference) so that an external control device can be used.

15. Claim 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view Del Toro (US 5,733,267).

Regarding claim 42, Lenker et al. teach: a system as claimed in claim 41 (as described above).

Lenker et al. do not teach: wherein the intermediate component comprises the handle.

Attention is drawn to Del Toro who teaches a three-layered catheter of similar design to Lenker et al. where the outer sheath is connected to the inner sheath by an external member at the proximal end of the catheter, where it could be grasped as part

of a handle component (Figure 4 #40, column 3 – lines 16 to 26). The external member also stabilizes the relative positions of the outer and inner sheaths.

It would therefore be obvious to one of ordinary skill in the art and having the teachings of Lenker et al. and Del Toro before him or her to have combined the invention of Lenker et al. with the external member of Del Toro as an obvious design choice for accomplishing the stated goal of Lenker et al. which is to fix the relative positions of the outer and inner sheaths (stabiliser and inner core, or journey sleeve and shaft).

16. Claims 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Klein et al. (US 5,002,558).

Regarding claims 48-49, Lenker et al. teach: a system as claimed in claim 47 (as described above)

Lenker et al. do not teach: wherein the stabiliser component is melded to the inner core; a system as claimed in claim 48 wherein the stabiliser component is melded by a welding, gluing, joining, laminating, or bonding process.

Attention is drawn to Klein et al. who teach that it is known in the art to join an outer sheath to a catheter by using biocompatible glue (column 4 – lines 6 to 9).

It would therefore be obvious to one of ordinary skill in the art and having the teachings of Lenker et al. and Klein et al. before him or her to have joined the stabiliser (which is an outer sheath) to the inner core of the catheter using biocompatible glue.

17. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Harvey et al. (US 4,607,868).

Regarding claim 56, Lenker et al. teach: A system as claimed in claim 1 wherein the stabiliser component comprises a tubular element (as described above).

Lenker et al. do not teach: and the tubular element has a tapered distal end.

Attention is drawn to Harvey et al. (US 4,607,868) who teach that it is well known in the medical art to make tube connections by tapering the end of a tube to fit into a leur adapter (column 1 – lines 27 to 30).

It would therefore be obvious to one of ordinary skill in the art and having the teachings of Lenker et al. and Harvey et al. before him or her to have connected the stabiliser (journal sleeve) of Lenker et al. to an introducer sheath, as that is a modification suggested by Lenker et al. (column 4 – lines 37 to 39), in order to make the connection via a leur adapter.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is 571-270-5034. The examiner can normally be reached on M-F, 7:30-5:00 (alternate Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Del Sole/

Supervisory Patent Examiner, Art Unit 4123